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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,212	12/04/2001	Jeong S. Lee	ACSC 60308 (2864)	7883

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12/31/2003

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EXAMINER

DESANTO, MATTHEW F

ART UNIT PAPER NUMBER

3763

DATE MAILED: 12/31/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/010,212

Applicant(s)

LEE ET AL.

Examiner

Matthew F DeSanto

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 6-8, 10-15, 20, 22, 34 and 36 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 41 is/are allowed.
- 6) ☒ Claim(s) 1-5, 9, 16, 23-33, 35 and 37-40, 42 is/are rejected.
- 7) ☒ Claim(s) 17-19 and 21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections –

35 USC § 102 or 35 USC § 103

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-5, 9, 16, 25, 27 – 33, 37-40, and 42 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Estrada et al. (USPN 6193686).

Estrada et al. discloses a balloon (15) catheter with an elongated shaft having an inflation lumen, a guide-wire receiving lumen, a proximal shaft section comprising a proximal tubular member, a distal shaft section comprising an outer tubular member, and an inner tubular member and a reinforcing member (27) formed of a first polymeric material (braided polyimide) having a glass transition temperature greater than the glass transition temperature of a second polymeric material (Nylon 12) forming the distal

portion of the proximal tubular member. (Figures 1 – 11, Column 5, lines 8-45, and entire reference).

The examiner would like to note, that since the materials are the same for the first and second polymeric material in this reference as the claimed invention, it would have been obvious as well as taken only routinely skill in the art to modify the first and second polymeric material to have the given characteristics of the claimed polymeric materials.

4. Claims 1-5, 9, 16, 25, 27 – 33, 37-40, and 42 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Happ et al. (USPN 6575958).

Happ et al. discloses a balloon (22) catheter with an elongated shaft having an inflation lumen, a guide-wire receiving lumen, a proximal shaft section comprising a proximal tubular member, a distal shaft section comprising an outer tubular member, and an inner tubular member and a reinforcing member (130) formed of a first polymeric material (col. 5, lines 49-68) having a glass transition temperature greater than the glass transition temperature of a second polymeric material (Nylon 12) forming the distal portion of the proximal tubular member. (Figures 1 – 19, Column 4, line 65 – Column 5, line 4, and entire reference).

The examiner would like to note, that since the materials are the same for the first and second polymeric material in this reference as the claimed invention, it would have been obvious as well as taken only routinely skill in the art to modify the first and

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second polymeric material to have the given characteristics of the claimed polymeric materials.

Claim Rejections - 35 USC § 103

5. Claims 1-5, 9, 23-33, 35, and 37-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Verbeek (USPN 5690613), and further in view of Rau et al. (USPN 6024722) and in view of Samuelson et al. (USPN 6,165,166).

Verbeek discloses a balloon (35) catheter with an elongated shaft having an inflation lumen, a guide-wire receiving lumen, a proximal shaft section comprising a proximal tubular member (50) with a mandrel (30), a distal shaft section comprising an outer tubular member (80), and an inner tubular member (70) and a reinforcing member (13,17) formed of a first polymeric material polymeric reinforcing member around or within the proximal portion of the inner tubular member or the distal portion of the proximal tubular member, wherein a second polymeric material is used to form the distal portion of the proximal tubular member, as well as having a mandrel within the inflation lumen. (Figures 1A, 1B, 1C, and entire reference), but the reference fails to disclose the polymeric reinforcing member is formed from a thermoset or thermoplastic polyimide, and wherein the second polymeric material is formed from a nylon or polyether block amide, polyurethane, and adhesive polymer and wherein the first polymeric material has a higher glass transition temperature than the second polymeric material.

Rau et al. discloses the use of thermoplastics and thermoset polyimide in balloon catheters because of the high strength and flexibility. (Column 1, line 32-45, and entire reference)

Samuelson et al. discloses a catheter with different layers and each layer has a different glass transition temperature, and wherein the outer layer has the greatest glass transition temperature, as compared to the inner most layer, which has the lowest glass transition temperature. The invention discloses that varying the glass transition temperature provides many advantages. (Column 4, lines 7-37).

At the time of the invention it would have been obvious for one of ordinary skill in the art to combine the teachings of Verbeek with the teachings of Rau et al. and Samuelson et al. because Rau et al. discloses the advantage of using a thermoset polyimide in a catheter wall because of the high strength and flexibility and Samuelson et al. disclosed using different polymers with different glass transition temperatures.

Allowable Subject Matter

6. Claims 17, 18, 19 and 21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. Claim 41 is allowed.

Response to Arguments

8. Applicant's arguments with respect to all the claims have been considered but are moot in view of the new ground(s) of rejection.

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9. The rejection of Happ et al. and Estrada et al. have been changed to include a different reinforcing structure, therefore overcoming the argument made in the last reply.


10. With regards to the 103 Rejection with Verbeek, Rau, and Samuelson et al. the examiner uses Rau to show that thermoplastics are used in balloon catheter because of the characteristics that are accompanied with them, such as increased strength but still enough flexibility to be used in a medical procedures (motivation to combine). The examiner then uses a new reference to show that there are catheters that have layers with different glass transition temperatures depending on the characteristics of each layer as well as the catheter as a whole.

11. The examiner is not sure or confused with how a catheter will have a reinforcing layer with a low glass transition temperature? Therefore, the examiner would assume that any layer that is being used as a reinforcing layer would inherently have a higher glass transition temperature then the surrounding more flexible layers. This is the basis for the 102/103 Rejection as well as the 103 Rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Matthew F DeSanto whose telephone number is 1-703-305-3292. The examiner can normally be reached on Monday-Friday 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 1-703-308-3552.


Matthew DeSanto
Art Unit 3763
December 29, 2003

